UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,434	10/02/2001	Kurt E. Petersen	22660-0028 DIV 3	5347

20350 7590 05/09/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/970,434
Filing Date: October 02, 2001
Appellant(s): PETERSEN ET AL.

Chung-Pok Leung
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 13, 2006 appealing from the Office action mailed February 7, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-26, 31, 32, 35, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522].

With respect to claims 21, 35, 40, Wilding et al teach a cartridge having a sample flow path (claim 1), lysing means (claim 2), filters (column 13, line 41 - column 14, line 13), beads for binding viruses and cell types (column 3, lines 58-62, column 13, lines 1-5), a waste chamber in fluid communication with the lysing chamber (column 13, lines 13-16), which has an external surface (figures 1, 2), a third chamber (PCR chamber) connected to the lysing means via an analyte flow path for receiving the analyte separated from the sample (claims 1-4), and a flow controller comprising valves that direct fluid flow in the system (claims 2, 3, column 14, lines 14-40). Wilding et al further teach optically detectable labels such as beads may be attached to a binding moiety to enhance detection of the polymerized polynucleotide (column 11, lines 40-49). Wilding et al fail to teach that a transducer coupled to the external surface of the wall.

Murphy et al, however, do teach that ultrasonic energy and lysing beads can be used for lysing cells without destroying the RNA and DNA once released (column 5, lines 5-20, claim 1). Murphy et al further teach that this ultrasonic energy may come from a suitable transducer attached to or in proximity to the well (column 7, lines 25-35). Murphy et al further teach that the low power density of the ultrasound bath of the present invention while sufficient to disrupt cells is not powerful to enough to destroy RNA or DNA once released, and that experiments have

shown that the method of the present invention is effective in disrupting cells at room temperature and above, thus allowing cells to be broken open in a rapid, safe, efficient and inexpensive manner (column 8, lines 1-18).

Therefore it would have been obvious in the method of Wilding et al to include beads and a transducer, as suggested by Murphy et al, in the lysing chamber, for lysing cells without destroying the RNA and DNA once released when subjected to ultrasonic energy from a transducer in a rapid, safe, efficient and inexpensive manner.

With respect to claims 22-24, Wilding et al further teach mesoscale polynucleotide polymerization reaction chambers which may be used for the rapid amplification of a polynucleotide, where the presence of amplified polynucleotide product can be detected by means of gel electrophoresis (column 10, lines 55-67). A mesoscale PCR chamber may be microfabricated with multiple sections, connected by flow channel (column 9, lines 50-61). In the first section, a pump delivers the polynucleotide sample and required PCR reagents (column 10, lines 65-67). In the second section, a continual polymerase chain reaction cycle is implemented (column 10, lines 1-5).

With respect to claim 25, Wilding et al teach a means for thermally regulating the contents of said chamber whereby the temperature is controlled to amplify said preselected polynucleotide (claim 8) and at least one optical detector for detecting the analyte (column 4, lines 46-62).

With respect to claim 26, Wilding et al further teach mesoscale polynucleotide polymerization reaction chambers which may be used for the rapid amplification of a polynucleotide (column 10, lines 55-67).

With respect to claim 31, Wilding et al teach sample chambers having a port for introducing a sample into the cartridge, a sample flow path, and a lysing chamber in the sample flow path (columns 15-16, example 2, fig. 12).

With respect to claim 32, Wilding et al further teach valves that allow ports connected to flow paths to be opened and closed (column 14, lines 14-25).

With respect to claim 37, Murphy et al teach that the walls are deflectable enough that the ultrasound waves are capable of imparting pulsatile motion to the beads, which are located within the chamber (column 7, lines 55-67).

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Carlin [*Ultrasonics*, 1960, McGraw-Hill].

With respect to claims 27, 28, Wilding et al and Murphy et al do not specifically teach the use of a wall that is dome-shaped and convex, and sufficiently deflectable to deflect in response to vibratory movements.

However, it would obvious to a person of ordinary skill in the art to use a wall that is dome-shaped and convex, as Carlin teaches the design of plastic lenses from glass, metals, and plastics such as plexiglass or polystyrene, in order to focus beams, which would be very valuable for agitational work, where a great amount of ultrasonic output is necessary (p. 89-90, 61-63).

Therefore it would be obvious to use a wall that is dome-shaped and convex, as taught by Carlin, in the cartridge of Wilding et al, in order to focus beams, where a great amount of ultrasonic output is necessary.

With respect to claim 29, the Wilding et al teaches a device where the device ranges from microns to a few millimeters in thickness (column 4, lines 55-60).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Bersted et al [US 6,129,879].

Wilding et al and Murphy et al, teach the use of lysing chambers, as discussed above. Wilding et al and Murphy et al do not specify that the lysing chamber comprises a wall comprised of a sheet or film of polymeric material

It is common to find PCR devices comprised of polymeric material such as polypropylene, since the surface of polypropylene is smooth and inert so does not readily bind enzymes and allows for easy recovery of products. Furthermore, Bersted et al teach that other advantages of polypropylene include low cost, ease of processing, strength, chemical inertness and hydrophobicity (column 1, lines 35-44).

Therefore, it would be obvious to use a wall comprised by a sheet or film of polymeric material, as taught by Bersted et al, in the device of Wilding et al, since the surface of polymeric material does not readily bind to enzymes and allows for easy recovery of products.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Lynnworth [US 4,335,719].

Wilding et al, Buechler et al, and Murphy et al teach the use of lysing chambers, but fail to teach the use of stiffening ribs.

Lynnworth, however, teaches that in order to increase the transmission through the shield at higher frequencies, or to reduce the mass of the shield, the shield thickness may be reduced considerably. Tube wall thickness as small as 0.1 mm are commonly available for many engineering materials. However, such thin walled tubes are not always adequate structurally, as their reduced stiffness is subject to vibratory motion.

Therefore the thin shield is reinforced or stiffened in one direction by ribs (column 12, lines 20-30). Therefore, it would be obvious to use stiffening ribs in the invention of Wilding et al, as taught by Lynnworth, in order to increase the transmission through the wall at higher frequencies.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Buechler et al [US 6,106,779].

With respect to claims 33-34, Wilding et al teach a cartridge having a sample flow path (claim 1), lysing means (claim 2), filters (column 13, line 41 - column 14, line 13), beads for binding viruses and cell types (column 3, lines 58-62, column 13, lines 1-5), a waste chamber in fluid communication with the lysing chamber (column 13, lines 13-16), which has an external surface (figures 1, 2), a third chamber (PCR chamber) connected to the lysing means via an analyte flow path for receiving the analyte separated from the sample (claims 1-4), and a flow controller comprising valves that direct fluid flow in the system (claims 2, 3, column 14, lines 14-40). Wilding et al fail to teach that the filter and beads are contained in the lysing chamber, nor does Wilding et al teach a transducer coupled to the external surface of the wall.

Buechler et al, however, teach that the use of filters and meshes for the lysing of cells and for removing component material (column 23, lines 10-35).

Therefore it would have been obvious in the method of Wilding et al to include filters, as suggested by Buechler et al in the lysing chamber, for lysing cells while also removing component material.

(10) Response to Argument

Applicants argue that neither Wilding et al nor Murphy et al teach a device having a lysing chamber containing at least one filter or beads for capturing the cells or viruses in a sample as the sample flows through the lysing chamber. Applicants refer to the separate cell separation chamber positioned upstream of the lysis chamber in Wilding et al as evidence that the capture material is not in the lysis chamber. This is not found persuasive, as the example cited by applicants is merely one embodiment used in Wilding et al. It should also be noted that applicants have merely recited that the capture material for capturing the cells or viruses comprises at least one filter or beads, and therefore any means capable of filtering or that is a bead would read upon the limitation.

As discussed above, Wilding et al also teach filters for filtering cell debris prior to polynucleotide analysis (column 13, lines 43-47), where the filters may be channels of reduced diameter (column 13, lines 46-51), which would include the channel exiting the lysing chamber. Wilding et al also teach paramagnetic or ferromagnetic beads with immobilized polynucleotide probes that can be transported throughout the flow system (column 14, lines 1-15), which would include the lysing chamber, which would also read upon the claims.

Murphy et al provides an alternative way of lysing cells involving beads and an ultrasound transducer, and further teach that the low power density of the ultrasound, while sufficient to disrupt cells is not powerful to enough to destroy RNA or DNA once released, and that experiments have shown that the method of the present invention is effective in disrupting cells at room temperature and above, thus allowing cells to be broken open in a rapid, safe, efficient and inexpensive manner (column 8, lines 1-18), releasing RNA and DNA for hybridization with complementary sequences of nucleic acids present in genetic probes or for releasing protein and cell components for antibody reactions (column 5, lines 60-67).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Nelson Yang

Conferees:

James Housel

Long Le

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/30/06

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600